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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/180,798	11/16/98	DE VRIES S	S-137-1103/S

001095
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EXAMINER	
MEHTA, A	
ART UNIT	**PAPER NUMBER**
1638	10

DATE MAILED: 08/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/180,798	De Vries et al
Examiner	**Group Art Unit**
Ashwin Mehta	1638

☒ Responsive to communication(s) filed on *Feb 16, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-46* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-46* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *15*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Specification

1. The specification should contain sub-headings, such as "Detailed Description of the Invention", "Brief Description of the Drawings", etc., in compliance with 37 CFR 1.77. See also MPEP 608.01(a).

2. Applicants are notified that the STIC Systems Branch detected and corrected errors in the submitted CRF. Specifically, STIC deleted non-ASCII "garbage" at the beginning/end of files.

3. The specification in numerous locations, such as pages 18, 25, and 26, contains amino acid or nucleotide sequences which are not identified by their SEQ ID NOs. Correction is required.

Claim Objections

4. Claims 5-15, 25-44, and 46 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must refer to other claims in the alternative only, and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

5. Claims 18-20, and claims dependent thereon, are objected to under 37 CFR 1.821 (d) for failing to identify the claimed nucleotide sequences by a SEQ ID NO.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 40 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. Claims 16-30, and 34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims read on a DNA per se which is found in nature and thus, is unpatentable to applicant. The DNA as claimed has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brodgex Co., 283 U.S. 2 (1931), Funk Brothers Seed Co. v. Kalo Inoculant Co., 33

U.S. 127 (1948), Diamond v. Chakrabarty, 206 USPQ 193 (1980). It is suggested that applicant use the language "isolated" or "purified" in connection with the DNA coding sequence to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

8. Claim 1 and claims 2-8, 41, and 46 dependent thereon are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the recovery of the apomictic seed. The preamble of claim 1 indicates a method for producing apomictic seed. However, the last step of the method of claim 1 is directed to the location of expression of the nucleotide sequence, not the recovery of seed.

9. Claim 10 and claims 11-15, 25-44, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "substantially similar" in lines 4-5 of claim 10 renders it and those dependent thereon indefinite. It is not clear what is encompassed by the recitation.

10. Claim 1 and dependent claims 2-15, 25-44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and those dependent thereon are indefinite because it is not clear in what cell types the transgene is intended to be expressed to produce the apomictic seeds. Part (I) of claim 1 indicates that the nucleotide sequence can be expressed in any cell and render it embryogenic, but part (iii) limits expression to the vicinity of the embryo sac.

11. Claim 12 and dependent claims 13-15, 25-44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is a "Markush"-type claims that employs improper Markush terminology. Examples of proper Markush terminology, for a hypothetical claim in which an item from a group consisting of A, B, C, and D, is to be chosen, are 1) the chosen item is A, B, C, or D; 2) the chosen item is selected from the group consisting of A, B, C, and D. See MPEP § 2173.05(h).

12. Claim 40 provides for the use of DNA in the manufacture of apomictic seeds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claims 41 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "obtainable" renders the claims and those dependent thereon indefinite. The term does not make clear whether or not the claimed apomictic seeds can be obtained by the method of the any one of claims 1-15 or 40. Further, the claims do not make clear what other method can be used to obtain the seeds if not from one of claims 1-15 or 40.

14. Claims 1 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "expressing" renders the claims and those dependent thereon indefinite. "Expressing" is not an active method step but rather a natural biological occurrence. In other words, the DNA sequence would be naturally expressed without any further interference or activity by the skilled artisan, and therefore cannot be considered a "step" in the claimed method.

15. Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "substantiall similar" renders the claims and those dependent thereon indefinite. The specification does not define "substantially similar". Therefore, it is not clear what proteins the claims are referring to.

16. Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "stringent conditions" renders the claims and those dependent thereon indefinite. Any two DNA sequences will hybridize to each other given the appropriate stringency. The claims should recite the high stringency conditions required to exclude binding of non-specific or undesirable DNA sequences, as described in the specification.

17. Claim 43 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivatives" in lines 4 and 5 of the claim renders it and those dependent thereon indefinite. It is not clear what is encompassed by the term. The metes and bounds of the claim are not clear.

18. Claims 16-34 and 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they lack an article. It is suggested, for example, that claim 16 be changed to start with --A DNA comprising---.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-23, 25-27, 29-44 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a method of producing apomictic seeds comprising transforming any plant material with any nucleotide sequence encoding a protein which renders any plant cell embryogenic; or any DNA comprising any sequence encoding a protein which renders any cell embryogenic; or wherein the protein is a leucine rich repeat receptor like kinase that optionally contains a ligand binding domain; or a DNA comprising any sequence coding SEQ

ID NO: 3, 21, 33, or a protein substantially similar thereto which is capable of being membrane bound and has kinase activity, or has the sequence depicted in SEQ ID NOs: 1, 2, 20, or 32, or is complementary to one which hybridizes to them and has membrane bound protein kinase activity; vectors containing said DNA sequences.

The only DNA sequences described by the specification that encode a membrane bound protein having kinase activity that is involved in plant embryogenesis are those within the sequence listing. Other such DNA sequences and which encode products that are substantially similar to SEQ ID NOs: 3, 21, or 33 or is complementary to those which hybridize to SEQ ID NOs: 1, 2, 20, or 32 and which retain the claimed function are not described and therefore not reduced to practice. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Also see Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims encompassing a multitude of DNA sequences encoding proteins that renders any type of cell embryogenic, is membrane bound and has kinase activity, and lack of guidance as discussed

above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

20. Claims 1-15, 24, 28-44 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a method of producing apomictic seeds comprising transforming any plant material with any nucleotide sequence encoding a protein which renders any plant cell embryogenic; or any DNA comprising any sequence encoding a protein which renders any cell embryogenic; or wherein the protein is a leucine rich repeat receptor like kinase that optionally contains a ligand binding domain; or a DNA comprising any sequence coding SEQ ID NO: 23, 25, 27, 29, or 31, or a protein substantially similar thereto which is capable of being membrane bound and has kinase activity, or has the sequence depicted in SEQ ID NOs: 22, 24, 26, 28, or 30, or is complementary to one which hybridizes to them and has membrane bound protein kinase activity; vectors containing said DNA sequences.

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., any nucleic acid that minimally contains the recited sequence or sequence fragment; the genus includes any full length gene which contains the sequence, any fusion constructs or cDNAs.

Polynucleotides that may comprise a sequence from SEQ ID NOs: 22, 24, 26, 28, or 30, or which encode a protein having the sequence depicted in SEQ ID NOs: 23, 25, 27, 29, or 31 are not described. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because the elected SEQ ID NOs are only fragments of any full-length gene or cDNA species (indicated on page 15). When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any necessary common attributes or features. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus of, e.g., "A cDNA comprising [a partial sequence]," encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of a full open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus, i.e., the elected SEQ ID NOs. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fusion proteins, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of the elected SEQ ID NOs do not provide an adequate description of the claimed genus "comprising" these sequences.

Weighing all factors, 1) partial structure of the DNAs that comprise the recited SEQ ID NOs and fragments, 2) the breadth of the claim as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and the function of the genes and/or fusion constructs, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise the elected SEQ ID NOs. Also see Fiers vs. Sugarno, *supra*. Given the breadth of the claims encompassing a multitude of DNA sequences encoding proteins that renders any type of cell embryogenic, is membrane bound and has kinase activity, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

21. Claim 1-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of producing apomictic seeds comprising transforming any plant material with any nucleotide sequence encoding a protein which renders any plant cell embryogenic; or a method of obtaining embryogenic cells in any plant material; or a method of generating somatic embryos under in vitro conditions wherein the SERK protein is overexpressed ectopically; or DNA comprising a sequence which renders any cell embryogenic; or DNA which render any cell embryogenic.

The specification is not enabled for a method of producing apomictic seeds, of obtaining embryogenic cells, or for generating somatic embryos by expressing the SERK protein in all cell types, as encompassed by the claims. The specification only teaches that the SERK protein is expressed in cells of the carrot hypocotyl that are competent to potentially become embryogenic, but it does not teach that expression of the SERK protein alone is sufficient for cells to become embyrogenic. The specification does not actually demonstrate that plant cells transformed with the nucleotide sequence encoding SERK rendered the cell embryogenic, nor does it demonstrate that a plant regenerated therefrom produced apomictic seed. Schmidt et al teach that the SERK gene is transiently expressed during embryogenesis and belongs to a class of embryo-expressed genes that are expressed during early embryogenesis (page 2060). It is therefore apparent that other gene products are also required for embryogenesis to occur. The teachings of the

specification only indicate that the SERK gene is a marker for the competent cell stage in somatic embryogenesis. Further, the biological function of the SERK protein is not known, nor is the identity of the ligand that binds it known (Schmidt et al, page 2060). Since SERK protein function is unknown, it is unpredictable whether it alone is capable of rendering any cell type embryogenic. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claims encompassing a method of producing apomictic seeds comprising transformation with any nucleotide sequence which renders a plant cell embyrogenic or a method of obtaining embryogenic cells or of producing somatic embyros comprising ectopically overexpressing the SERK gene, unpredictability of the art and lack of guidance as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

22. Claims 6 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of producing apomictic seeds comprising transforming any plant material with any nucleotide sequence encoding a protein which renders any plant cell embryogenic wherein the nucleotide sequence encodes a protein lacking a ligand

binding domain; or a DNA encoding a protein capable of rendering any cell embryogenic wherein the protein leucine rich repeat (LRR) receptor like kinase that may or may not have a ligand binding domain.

As discussed above, the specification does not teach DNA which, when alone transgenically expressed in any cell, renders that cell embryogenic. The specification also does not provide any teaching demonstrating that a DNA encoding a LRR protein kinase which lacks a ligand binding domain may render a cell embryogenic, and lead to apomictic seed production in transgenic plants. The specification on page 3 only suggests that the protein kinase is either not present or is functionally inactive. The only reasoning offered for this assumption is a statement of page 3 indicating that the extracellular domain of many kinases acts as an inhibitor of the kinase domain in the ligand-free state. No supporting evidence is offered for this statement. Nevertheless, it is still inaccurate to simply assume that the kinase would be in a constitutively active form in the absence of a functional ligand binding domain. No evidence is offered indicating that the kinase would be in an active form once freed of a functional ligand binding domain. Further, the specification does not teach what the sequences encoding the ligand binding domain are, so that one skilled in the art may remove them. Nor does it teach how to alter the binding domain to render it functionally inactive while also rendering the kinase domain constitutively active. Undue experimentation would be required by one skilled in the art to make these determinations. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an]

enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claims encompassing a method of producing apomictic seeds comprising transformation of cells with a nucleotide sequence encoding an LRR protein kinase lacking a functional ligand binding domain, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

23. Claims 16-44 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards any DNA comprising any sequence encoding a protein which renders any cell embryogenic; or wherein the protein is a leucine rich repeat receptor like kinase that optionally contains a ligand binding domain; or a DNA comprising any sequence coding SEQ ID NO: 3, 21, 33, 23, 25, 27, 29, or 31, or a protein substantially similar thereto which is capable of being membrane bound and has kinase activity, or has the sequence depicted in SEQ ID NOs: 1, 2, 20, 22, 24, 26, 28, 30, or 32, or is complementary to and hybridizes to them and has membrane bound protein kinase activity; vectors containing said DNA sequences.

As discussed above, the specification does not enable DNA sequences which alone render any cell embryogenic; teaches that the SERK gene is involved in embryogenesis and can be a marker for competent plant cells that potentially may become embryogenic. Given that the function of and ligands that bind SERK are unknown (Schmidt et al, page 2060), it is not clear how one skilled in the art would make DNA that encode proteins having sequences that are substantially similar to those of SEQ ID NOs: 3, 21, and 33, or are complementary to sequences that hybridize to SEQ ID NOs: 1, 2, 20, and 32, and still retain the claimed property of rendering any cell embryogenic. See Genentech, Inc. V. Novo Nordisk, A/S, *supra*. Further, claims 25-28 encompass sequences which hybridize to the stated SEQ IDs at any stringency. It is well known in the art that unrelated DNA sequences will hybridize to any DNA at low and moderate stringencies. Furthermore, the specification on page 15 indicates that SEQ ID NOs: 22, 24, 26, 28, and 30, which encode SEQ ID NOs: 23, 25, 27, 29, and 31, are ESTs. The specification does not teach that these partial DNA sequences, or the amino acid sequences they encode, have the same properties of the protein encoded by the full length *Dauscus carota* SERK gene. It is not clear how partial DNA fragments can encode proteins which have the claimed function. Given the breadth of the claims encompassing nucleotide sequences which are complementary to those which hybridize to or encode proteins substantially similar to those in the sequence listing and render any cell embryogenic, and encompassing the sequences of SEQ ID NOs: 22-31 which are ESTs and their predicted amino acid sequences, the unpredictability in the art and lack of

guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 21-29, 32, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al.

The claims are broadly drawn towards any DNA comprising a nucleotide sequence depicted in or encoding a protein having the sequence depicted within SEQ ID NOs: 1-3, 20-32, or encoding a protein substantially similar thereto, or having a nucleotide sequence complementary to that which hybridizes thereto, and which have membrane bound kinase activity.

Song et al teaches the rice *Xa21* gene, which is a receptor protein kinase, and carries a leucine-rich repeat motif. The *Xa21* gene and its encoded protein product are encompassed by the claims.

CLOSING REMARKS

Any inquiry concerning this communication should be directed to Examiner Ashwin Mehta, whose telephone number is (703) 306-4540. The Examiner can normally be reached Monday-Friday, from 8:30 A.M. - 5:00 P.M. The fax phone number for the group is (703) 305-3014. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Amy Nelson

AMY J. NELSON, PH.D
PRIMARY EXAMINER

Ashwin D. Mehta

July 28, 2000